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Room 1061  
Rockville, MD 20852

RE: Docket #: 94N-4845

Dear Sirs:

As a practicing orthopaedic surgeon, I feel obliged to register my opinion that it would be inappropriate to proceed with the proposed FDA regulations regarding utilization of bone allograft as medical devices.

It is currently difficult enough to obtain satisfactory bone tissue on a regular basis and the cost is rather high. In addition, review of the literature and my own personal experience supports the conclusion that the methods of obtaining, processing and utilizing bone allograft material is working well with very few complications. It is difficult to understand how a whole body of new regulations would improve the current system. If there are some specific areas of difficulty in obtaining and processing of these tissues, then those could probably be best managed by specific changes directed at those problem areas (although I am certainly not aware of any major problem areas).

Therefore, in summary, I would like to strongly urge the attempts at the proposed regulatory actions be dismissed.

Sincerely,

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NAJ/vlf

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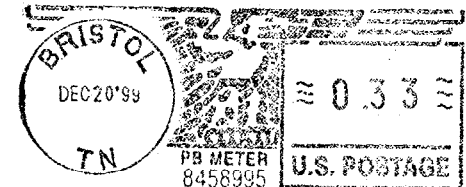
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